12/22/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED RK

November 28, 1997

cc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 11

Larry Rentfro
Chief Executive Officer
Grant Regional Health Center
507 South Monroe Street
Lancaster, Wisconsin 53813

Dear Mr. Rentfro:

Your mammography facility (MQSA #175885) was inspected on November 20, 1997, by a representative of the State of Wisconsin acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. A radiological technologist, [redacted] who has been performing mammography is neither licensed by a state, nor board certified by any of the FDA-approved professional boards.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

* impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;

* suspend or revoke a facility's FDA certificate for failure to comply with the Standards;

* seek an injunction in Federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of the specific steps you have taken to correct all of the violations noted in this letter and each step your facility is taking to prevent the recurrence of similar violations. If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Tom Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Milwaukee, WI 53226-1305. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Tom Garvin at (414)771-7167 ext. 12.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

TWG/ccl

xc: Paul Schmidt
Chief, Radiation Protection Unit
State of Wisconsin
P.O. Box 309
Madison, WI 53701